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| APPLICATION NO.   | FILING DATE                          | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO    |  |
|---|--------------------------------------|----------------------|---------------------|--------------------|--|
| 10/671,007  | 09/25/2003                           | Wendy H. Raskind     | UWOTL121680         | 8123               |  |
| 26389<br>CHRISTENSE   | 7590 08/30/2007<br>N O'CONNOR IOHNSO | EXAM                 | EXAMINER            |                    |  |
| CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC<br>1420 FIFTH AVENUE |                                      |                      | JOHANNSE            | JOHANNSEN, DIANA B |  |
| SUITE 2800<br>SEATTLE, WA 98101-2347                                |                                      | ART UNIT             | PAPER NUMBER        |                    |  |
|   |                                      |                      | 1634                | <u> </u>           |  |
|   |                                      |                      | <b></b>             |                    |  |
|   |                                      |                      | MAIL DATE           | DELIVERY MODE      |  |
|   |                                      |                      | 08/30/2007          | PAPER              |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|--|--|---|
| •  | Application No.  | Applicant(s)  |
| Office Action Com  | 10/671,007   | RASKIND ET AL.  |
| Office Action Summary  | Examiner   | Art Unit  |
|  | Diana B. Johannsen   | 1634  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with th  | e correspondence address  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICAT 36(a). In no event, however, may a reply built apply and will expire SIX (6) MONTHS to cause the application to become ABANDO | ION. e timely filed rom the mailing date of this*communication. DNED (35 U.S.C. § 133). |
| Status   |  |   |
| 1) Responsive to communication(s) filed on 15 Ju   | ine 2007.  |   |
| · _ · _ ·  | action is non-final.   |   |
| 3) Since this application is in condition for allowar  | nce except for formal matters,   | prosecution as to the merits is   |
| closed in accordance with the practice under E   | x parte Quayle, 1935 C.D. 11   | , 453 O.G. 213.   |
| Disposition of Claims  |  |   |
| 4)⊠ Claim(s) <u>1,2,4-6 and 43-46</u> is/are pending in th   | e application  |   |
| 4a) Of the above claim(s) is/are withdraw  |  | ,   |
| 5) Claim(s) is/are allowed.  |  | •   |
| 6) Claim(s) is/are rejected.   |  |   |
| 7) Claim(s) is/are objected to.  |  |   |
| 8) Claim(s) 1,2,4-6 and 43-46 are subject to restri  | iction and/or election requirem  | ent.  |
| Application Papers   |  |   |
| 9) The specification is objected to by the Examine   | r  |   |
| 10) The drawing(s) filed on is/are: a) acce  |  | ne Examiner   |
| Applicant may not request that any objection to the  | •  |   |
| Replacement drawing sheet(s) including the correct   |  | <b>, ,</b>  |
| 11)☐ The oath or declaration is objected to by the Ex  | aminer. Note the attached Off  | ice Action or form PTO-152.   |
| Priority under 35 U.S.C. § 119   |  |   |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:   | priority under 35 U.S.C. § 119   | ∂(a)-(d) or (f).  |
| 1. Certified copies of the priority documents  | s have been received.  |   |
| 2. Certified copies of the priority documents  | s have been received in Applic   | cation No   |
| 3. Copies of the certified copies of the prior   | ity documents have been rece   | eived in this National Stage  |
| application from the International Bureau  | , , ,  |   |
| * See the attached detailed Office action for a list   | of the certified copies not rece   | eived.  |
|  |  |   |
|  |  |   |
| Attachment(s)  |  |   |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 4) Interview Summ<br>Paper No(s)/Ma  |   |
| 3) Information Disclosure Statement(s) (PTO/SB/08)   | 5) Notice of Inform  | al Patent Application   |
| Paper No(s)/Mail Date  | 6)   |   |

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## **DETAILED ACTION**

1. This action is responsive to the Amendment and Response filed June 15, 2007. Claims 1-2 and 4-6 have been amended, claims 3 and 7-42 have been cancelled, and claims 43-46 have been added. Applicant's amendments, and particularly the addition of new claims 43-44, necessitate a further restriction as set forth below.

## Election/Restrictions

2. Applicant has added new claims 43-44, such that the claims of elected Group I now encompass a multitude of distinct exon sequences contained within SEQ ID NO: 3, as well as all possible combinations thereof. Whereas the claims of Group I previously required only a single sequence search aimed at identifying prior art meeting the limitations of claims 7-8 (requiring sequences 90% or 95% identical to SEQ ID NO: 3 over its entire length), a search of the claims as amended would require 18 separate sequence searches and consideration of any prior art relevant to each sequence searched. The 18 different exon sequences encompassed by the claims, and the various combinations thereof also encompassed by the claims, differ in sequence and structure from one another, and possess different functional properties and characteristics. In accordance with the policy set forth in 1316 OG 122 (27 March 2007), claims directed to polynucleotide molecules are considered for independence, relatedness, distinction and burden as for claims to any other type of molecule. In the instant case, methods employing each of the sequences and combinations of claims 43-44 each constitute a distinct invention. Further, as each sequence/combination would

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require a different sequence search, a search of more than one such sequence/combination would pose a serious burden on the examiner and on the Office.

- 3. Accordingly, Applicant must further elect a single sequence or combination of sequences as set forth in claims 43-44 for examination. This is not an election of species. Applicant is advised that examination of the claims noted above will be restricted to the elected sequence/combination.
- 4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:
  - (a) the inventions have acquired a separate status in the art in view of their different classification;
  - (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
  - (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
  - (d) the prior art applicable to one invention would not likely be applicable to another invention;
  - (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Diana B. Johannsen Primary Examiner Page 5

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